

Amendments to the Drawings.

The attached replacement drawing sheet includes changes to FIG. 2. This sheet replaces the original drawing sheet including FIG. 2. In FIG. 2, the graph has been redrawn to clearly show the bars and numbers, and to remove the dark background, as requested in the Office Action.

Attachment: Replacement Drawing Sheet

Remarks

Claims 1, 2, 4-9, 11-15, 18 and 19 are under consideration.

Claims 3, 10, and 16-17 have been canceled without prejudice in order to expedite the further prosecution of this application.

New claims 18 and 19 have been added, which are directed to preferred embodiments of the present invention.

Applicants thank the Examiner for the helpful suggestions regarding the wording of the claims, which have adopted in the present amendments. Where applicable, the claims also have been amended to replace the word "whereby" with the word "wherein" and Markush language has been modified to more closely follow U.S. claiming practice.

Claim 1 has been amended to incorporate the limitation of canceled claim 3, to replace the phrase "is derived from" with "comprising", to specify that the vector is an isolated vector, and to clarify that the deletion in the *env* gene renders the envelope protein non-functional. Support for these amendments can be found in original claims 1 and 3 and in the specification on page 3, lines 26-31 and page 6, lines 11-18.

Claim 4 has been amended to clarify that the deletion is in the *env* gene, rather than of the *env* gene, as suggested by the Examiner.

Claim 6 has been amended to delete the article "the" before "SIVsmmPBj14" and to delete the second appearance of the word "virus", for clarity.

Claim 9 has been amended to adopt the Examiner's suggestion that the word "virus" in step (a) be replaced with the phrase "viral genome", and to delete the phrase in step (b) that recites "derived from". Claim 9 was also amended to specify that the viral envelope protein is a non-SIVsmmPBj14 envelope protein (see e.g., page 5, lines 9-11, and page 6, lines 20-27, which describes embodiments in which the envelope protein of the vector is from a virus other than SIVsmmPBj14). Claim 9 also incorporates the limitation of canceled claim 10.

Claims 12 and 13 have been amended for clarity and consistency with the changes in claim 9, from which they depend.

Claim 14 has been amended to recite "made according to the method" as suggested by the Examiner.

Claim 15 has been amended so that it now is directed to a method, rather than a use, and refers to the vector of claim 14, rather than claim 9, which is a method claim. Support for this amendment can be found in the working examples on page 7, line 10 through page 8, line 10.

New claim 18 is specifically directed to an isolated lentiviral vector that is capable of transducing cells in a G₀ phase. The lentiviral vector comprises a SIVsmmPBj1.9 lentivirus comprising an inactive SIVsmmPBj1.9 *env* gene, and an active VSV-G *env* gene, such that the envelope proteins of the vector are VSV-G envelope proteins. New claim 19 depends on claim 18 and specifies that the inactive SIVsmmPBj1.9 *env* gene comprises a deletion in the SU region thereof. Support for claims 18 and 19 can be found in the specification on pages 6-8, in the working examples.

No new matter is added by any of these amendments.

Substance of Interview with the Examiner.

Applicants' representative, Robert J. Ross, contacted Examiner Marvich by telephone on October 10, 2007 to request that the enablement rejection be clarified, since the copy of the Office Action received by Applicants and posted on PAIR did not identify which claims were rejected on this ground. Examiner Marvich agreed that the version of the Office Action received by Applicants and posted on PAIR was incomplete, and subsequently transmitted a complete version of the Office Action to Applicants. This response is based on the complete Office Action received on October 12, 2007.

Claim Objections.

Claims 4, 9, and 14 stand objected to for various grammatical and syntax informalities. In particular, claim 4 was objected use of the phrase "deletion of the". The Examiner suggested rewording the phrase to read "deletion in the". The claim has been amended as suggested. The Examiner also suggested that claim 9 be amended to replace the word "virus" in step (a) with the phrase "viral genome", and to delete the phrase in step (b) that recites "derived from". Claim 9 has been amended accordingly.

In addition, the Office Action indicated that claim 14 be amended for clarity. In response, claim 14 has been amended to recite "made according to the method" as suggested by the Examiner.

Rejections Under 35 U.S.C. §101.

Claims 1 and 2 stand rejected as being drawn to non-patentable subject matter because the claims allegedly encompass naturally-occurring viruses. The Examiner suggested that the claims be amended to specify that the viral vector is "isolated" to overcome the rejection. Applicants have adopted this suggestion.

Claim 15 stands rejected as being drawn to non-patentable subject matter because the claim was directed to a *use* of the vector, without reciting any steps. In response, claim 15 has been revised to convert the claim into a method for transducing cells in the G₀ phase, comprising contacting the cells with a vector of claim 14. Accordingly, withdrawal of this rejection is warranted.

Rejections Under 35 U.S.C. §112.

Claims 1, 2, and 4-15 stand rejected under the second paragraph of 35 U.S.C. §112 as allegedly being indefinite. Claims 1 and 9 were objected to as being unclear for including the phrase "derived from". In response, claim 1 has been amended to delete this phrase and replace it with "comprising." Claim 9 has been amended to specify that the viral envelope protein is a non SIVsmmPBj14 envelope protein, and to delete the phrase that recites "derived from."

Claims 15-17 were objected to for being directed to a "*use*" of the vector. In response, claim 15 has been rewritten as a method claim, i.e., a method for transducing cells in the G₀ phase, comprising contacting the cells with a vector of claim 14. Claims 16 and 17 have been canceled.

Claims 1-14 stand rejected under the first paragraph of 35 U.S.C. §112 as allegedly not being in compliance with the enablement requirement. According to the Office Action, the specification is enabling for a recombinant SIVsmmPBj14 or SIVsmmPBj1.9 virus, or for a method of making pseudotyped vectors from these viruses, in which the SIVsmmPBj14 virus envelope gene is deleted such that the envelope protein is non-functional. The Office Action also alleged that the claims were not enabled for the full scope of vectors "derived from" SIVsmmPBj14, however. In response, claim 1 has been amended to specify that the claimed vector is a SIVsmmPBj14 virus in which at least a portion of the *env* gene has been deleted to render the envelope protein encoded by the gene non-functional.

These amendments are supported by the working examples, on pages 6-8, in which a portion of the SIVsmmPBj14 *env* gene (i.e., a portion in the SU region) was deleted to render the envelope protein non-functional. In addition, claim 4 specifies a location for the deletion (i.e., in the SU region). The claims are no longer directed to a vector "derived from" SIVsmmPBj14.

At the time the invention, one of ordinary skill in this field would have had an advanced degree in virology or molecular biology. Thus, the person of ordinary skill would have readily understood the nature of the deletions specified by the claims, since the *env* gene was known at the time of the invention and the application explains the purpose of the deletion, i.e., to render the envelope protein non-functional. In addition, the application provides working examples in which the deletion is made in the SU (surface protein) region, as specified in claim 4. While some experimentation might be needed to practice embodiments of the invention beyond what is specifically disclosed in the examples, one of ordinary skill in the art would have found such experimentation (i.e., cleaving the DNA of the gene with various restriction enzymes, rejoining the cleaved ends, and determining whether a functional envelope protein is expressed from the resulting recombinant gene) to be routine, since all of methods and processes were routinely performed at the time of the invention. Enablement is not precluded by the necessity for some experimentation, so long as the experimentation is not 'undue'. See *In re Wands*, 858 F.2d 731, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988). The test is not merely quantitative, since a considerable amount of experiment is permissible, if it is merely routine, or if the specification in question provides a reasonable amount of guidance. *Id.* Accordingly, the specification would have provided adequate guidance to one of ordinary skill in the art to practice the claimed invention without undue experimentation in this case, due to the state of the art, the level of skill in the art, and the guidance of the working examples. This is particularly true of claim 4, in which the region for the deletion is specified (i.e., the SU region). Similarly, new claims 18 and 19 are closely based on the working examples found on pages 6-8, which certainly provide sufficient guidance for one of ordinary skill to have practiced the claimed invention.

Withdrawal of this rejection is requested.

Rejections Under 35 U.S.C. §102.

Claims 1, 2, 5, 7, and 8 stand rejected as allegedly being anticipated by Verma *et al.* (US 6,013,516). Claim 1 has been amended to incorporate the limitation of claim 3, i.e.,

that at least part of the SIVsmmPBj14 *env* gene is deleted from the viral vector. Claims 2, 5, 7, and 8 each depend on claim 1 and thus include this limitation as well. Verma *et al.* does not teach or suggest such a deletion. Accordingly, this rejection should be withdrawn.

Claims 1 and 2 also stand rejected as allegedly being anticipated by McClure *et al.* (US 5,212,084). This reference does not teach or suggest deletion of a portion of the *env* gene from SIVsmmPBj14. Accordingly, this rejection should be withdrawn as well.

Conclusion.

Applicants request reconsideration, allowance of all claims, and early passage of the application to issue.

Respectfully submitted,

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By Talivaldis Cepuritis
Talivaldis Cepuritis (Reg. No. 20,818)

OLSON & HIERL, LTD.
20 North Wacker Drive
36th Floor
Chicago, Illinois 60606
(312) 580-1180